IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FERRING PHARMACEUTICALS INC. and REBIOTIX INC. Plaintiffs, v. FINCH THERAPEUTICS GROUP, INC., FINCH THERAPEUTICS, INC., and FINCH THERAPEUTICS HOLDINGS, LLC. Defendants.	)	C.A. No. 21-1694-JLH
FINCH THERAPEUTICS GROUP, INC., FINCH THERAPEUTICS, INC., FINCH THERAPEUTICS HOLDINGS, LLC, and THE REGENTS OF THE UNIVERSITY OF MINNESOTA, Counterclaim-Plaintiffs/Reply Defendants, v. FERRING PHARMACEUTICALS INC., and REBIOTIX, INC. Counterclaim-Defendants/Reply Plaintiffs.	)	

UMN AND FINCH'S BRIEF IN OPPOSITION TO
FERRING'S MOTION FOR JUDGMENT AS A MATTER OF LAW

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TABLE OF ABBREVIATIONS

Finch	Finch Therapeutics, Inc., Finch Therapeutics Group, Inc.
UMN	Regents of the University of Minnesota
Ferring	Ferring Pharmaceuticals Inc.
Rebiotix	Rebiotix Inc.
’080 patent	U.S. Patent No. 11,541,080
’309 patent	U.S. Patent No. 10,675,309
UMN Patent	U.S. Patent No. 10,251,914
patents-in-suit	U.S. Patent Nos. 10,675,309; 11,541,080; 10,251,914
POSA	Person of ordinary skill in the art
PTO	United States Patent and Trademark Office
FMT	Fecal microbiota transplant
HCP	Healthcare provider
rCDI	recurrent *Clostridium difficile* infection
CDI	*Clostridium difficile* infection
PEG	Polyethylene glycol
JMOL	Judgment as a matter of law
Br.	D.I. 502, Ferring’s Opening Brief in Support of its motion for Judgment as Matter of law Under Fed. R. Civ. P. 50(b)
Tr.	Trial transcript
Hamilton 2012	Hamilton et al., Standardized Frozen Preparation for Transplantation of Fecal Microbiota for Recurrent *Clostridium difficile* Infection, AM. J. GASTROENTEROLOGY. 1-12 (2012)
Hlavka Reference	WO 2011/094027 A1
Lee Jones	Ferring fact witness, founder of Rebiotix
Michael Berman	Ferring fact witness, founder of Rebiotix

Courtney Jones	Ferring fact witness, associate director of Rebiotix
Kristin Wannerberger	Ferring fact witness, appearing by deposition, director of Ferring
Edwin Hlavka	VP of ConcepTx Medical
Dr. Robert Britton	Ferring technical expert witness
Dr. Richard Johnson	Ferring technical expert witness
Dr. Todd Treangen	Ferring technical expert witness
Douglas Kidder	Ferring damages expert witness
Dr. Alex Khoruts	UMN fact witness, inventor
Dr. Michael Sadowsky	UMN fact witness, inventor
James Burgess	Finch fact witness, Finch co-founder and former VP of Innovation,
Mark Smith	Finch fact witness, appearing by deposition, Finch co-founder
Andrew Benson	UMN and Finch technical expert witness
Neil Stollman	UMN and Finch technical expert witness
James Malackowski	UMN and Finch damages expert witness

I. Introduction

After a five-day trial, the eight-member jury unanimously decided that Ferring willfully infringes both UMN and Finch's patents, rejected Ferring's argument that every asserted claim of each of those patents is invalid, and awarded UMN and Finch $25.8 million in damages (a little less than half the amount sought). Ferring's renewed motion for JMOL asks the Court to reverse nearly every aspect of the jury's verdict, re-raising many issues that have already been—often repeatedly—rejected by the Court, and seeking to render the jury's verdict a nullity. None of Ferring's arguments comes close to meeting the heavy burden needed to set aside the jury's verdict, and its last-ditch attempt to avoid the consequences of its willful infringement should be denied.

II. Legal Standard

JMOL "should be granted sparingly" and only where the record is "critically deficient of the minimum quantum of evidence in support of the verdict." *Eshelman v. Agere Sys., Inc.*, 554 F.3d 426, 433 (3d Cir. 2009). "[T]he evidence" must be viewed "in the light most favorable to the nonmovant" and the jury must be given "the advantage of every fair and reasonable inference." *Osseo Imaging, LLC v. Planmeca USA Inc.*, 116 F.4th 1335, 1340–41 (Fed. Cir. 2024) (citation omitted). "In performing this narrow inquiry," the court "must refrain from weighing the evidence, determining the credibility of witnesses, or substituting [its] own version of the facts." *Id.*

III. The Court Should Deny Ferring's JMOL of No Written Description (UMN Claim 7)

Ferring wrongly asserts that the following elements of claim 7 are not "adequately described": (1) the Markush group, requiring at least 6 of 10 enumerated bacterial classes; and (2) the claimed 10% reduction in Proteobacteria. At trial, Finch presented substantial evidence demonstrating the UMN patent discloses—via detailed processes and patient-level taxonomic and clinical data—that the inventors described and possessed the claimed invention, and the jury

rightly agreed. The UMN inventors testified about their years developing the claimed processes, and their methodologies and clinical work confirming the efficacy of their patented approach through multiple examples and other disclosures in their patent. *E.g.*, Tr. 96:8-99:24, 103:25-104:22, 188:24-189:17, 192:23-194:24; JTX-1, Fig. 1, 17:60–19:35, 19:39–26:54. The jury weighed the factual evidence and appropriately rejected Ferring's written description defense concluding Ferring did not prove invalidity by clear and convincing evidence. Giving full credit and deference to the jury's weighing of this evidence is consistent with the Court's rejection of Ferring's nearly-identical summary judgment motion. D.I. 492 at 28:17-29:13; D.I. 421 at 2. Ferring's repeat request for the Court to re-weigh the evidence is not a proper JMOL ground.

Ferring concedes that written description is a fact issue for the jury (Br. 4); on JMOL, the only issue is whether substantial evidence supports the jury's verdict. *Union Oil Co. v. Atl. Richfield Co.*, 208 F.3d 989, 997 (Fed. Cir. 2000). There is no separate, lower JMOL standard for written description and none of Ferring's cases (Br. 4) say otherwise.[1] Rather, given the clear and convincing standard, Ferring's burden to overturn the jury's verdict is "***doubly*** high." *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1353 (Fed. Cir. 2003).

For the Markush group, the patent fully describes the claimed bacterial classes. Claim 7 recites "a fecal extract or preparation comprising a fecal donor's intestinal microbiota comprising at least 6 different classes of bacteria" from ten enumerated classes. JTX-1. The 6 classes

[1] Ferring's cases are also inapposite, as the patents had ***no*** relevant disclosure or, at best, a disclosure of a small number of species, with others ***yet to be discovered***. *See Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1342 (Fed. Cir. 2021) (possible species vast and undisclosed); *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1164 (Fed. Cir. 2019) (no indication that undisclosed species were effective); *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1348 (Fed. Cir. 2013) (patent lacked disclosure of any variant that satisfies the claims); *Centocor Ortho Biotech, Inc. v. Abbott Lab'ys*, 636 F.3d 1341, 1350–51 (Fed. Cir. 2011) (similar); *Ariad Pharms., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1358 (Fed. Cir. 2010) (specification "hypothesizes with no accompanying description").

themselves are expressly described in the patent and claimed by name. *Id.* 5:25–29, 7:37–8:19, cl. 4. Moreover, the specification provides detailed descriptions to ensure the claimed fecal extract includes those 6 classes of bacteria, *e.g.*, via extensively described protocols for (1) donor screening to weed out fecal donors that would not produce the claimed bacterial results, *id.* (Ex. 2); and (2) processing the fecal material to arrive at the claimed composition, *id.* (Exs. 3–4). As inventor Dr. Sadowsky testified, by following the described "donor selection protocol" "and purify[ing] the microorganisms as [] instructed, [in] the patent, [a POSA] will always obtain at least 6 and usually more than those classes." Tr. 189:2–14; *id.* 187:4–9, 194:5-14. Indeed, Ferring's expert confirmed that healthy donors have 6 of 10 claimed bacterial classes, and does not dispute that the processing protocol keeps them intact. Tr. 852:11–22 (Treangen).

Finch likewise presented substantial evidence for the claimed 10% reduction in Proteobacteria. As inventors Drs. Khoruts and Sadowsky testified, the specification explains how they obtained the claimed changes and supports that description with substantial, concrete data from actual patients. Tr. 104:6-22, 156:18-158:12, 192:23-194:24; JTX-1 Fig. 1, 17:9-29, Tbl. 3. Example 4 "reports clinical experience with 43 consecutive patients." JTX-1, 19:66-67, Tbl. 3. Dr. Sadowsky testified a POSA would recognize these patients received at least 6 claimed classes, ***and*** "[a]bsolutely" achieved the claimed result. Tr. 192:23-194:24; *see id.* 352:12–353:19. Moreover, Example 1's Figures 1 and 2 depict the changes in relative abundance seen in the gut of an FMT recipient. JTX-1, 6:39–46. The text accompanying these figures explains that, before transplantation, "***[g]reater than 40% of the sequences obtained from the recipient's pretransplantation sample . . . belonged to*** [ ] Mollicutes strains or the ***Gammaproteobacteria***," whereas after transplantation, the "recipient's post-transplantation samples were dominated by Firmicutes." JTX-1, 17:21–29; *see also id.* 2:54–62. As Dr. Khoruts explained, a POSA would

read the foregoing together with Figures 1 and 2 and understand the inventors showed at least a 10% reduction in relative abundance of proteobacteria. Tr. 156:18–158:12.

Ferring's primary response is that the bar charts in Figures 1 and 2 are illegible. That is incorrect and expressly rebutted by Dr. Khoruts' testimony above. Moreover, while Dr. Treangen testified that he was unable to interpret Figure 1, his examination established that he used the same types of figures in his ***own*** papers, because they were the "standard." Tr. 862:7–863:6. This confirms that Ferring's argument is not appropriate for JMOL, but rather requires the jury to weigh the evidence and assess witness credibility. *See* D.I. 482 § 4.1 (jurors "are the ***sole*** judges of the credibility"). Ferring's other argument—that Example 1 can be disregarded because it only involved one patient—finds no support in the law. And while Ferring attempts to make a factual argument about what weight Example 1 should receive based on its sample size and how the material was processed, the jury rejected that argument. This makes good sense in view of other extensively described protocols (e.*g.*, JTX-1, Exs. 3, 4) and clinical evidence (*e.g.*, a 43-person study) demonstrating a "transition from theory to practice" (Br. 12 (citing *Ariad*, 598 F.3d at 1359)) using the patent's processing method. Ferring's argument that Example 4 lacks "taxonomic data" is wrong too. Br. 11. Ferring ignores Dr. Sadowsky's testimony that successes reported in Example 4 reflect application of the claimed methodology resulting in the claimed 6 classes of bacteria and reduction in Proteobacteria. Tr. 189:2–17, 194:23-194:24. Ferring's reliance on language from the specification concerning Example 4's "limitations" is unavailing, Br. 11, as the inventors merely noted that the identity of therapeutically important ***species*** (not ***classes***) remains to be investigated. Finch introduced substantial evidence of written description, and Ferring's request that the Court re-weigh the evidence is improper. *Union Oil*, 208 F.3d at 997–98; *Wang Lab'ys, Inc. v. Toshiba Corp.*, 993 F.2d 858, 866 (Fed. Cir. 1993); *Bd. of Regents v. Bos. Sci.*

Corp., 2024 WL 2848471, at *6-7 (D. Del. June 5, 2024).

Ferring's other arguments do not justify overturning the verdict. ***First***, Ferring contends that, because there are "multiple species" of bacteria per "class," UMN failed to show "either a representative number of species representing the full scope of the claim or common structural features by which a POSA could identify members of the genus." Br. 5-6. The Court rejected this exact argument at summary judgment. D.I. 258 at 13; D.I. 492 at 28:17-29:13; D.I. 421 at 2. The claims are directed to bacterial ***classes***, not species. Tr. 855:22–25 (Treangen). The evidence showed healthy microbiomes contain at least 6 of these 10 ***classes*** of bacteria, and the specification explains how to identify such healthy microbiomes and protect the classes during processing. Tr. 96:8-99:19, 187:4-9, 189:2-17, 192:23-194:14, 852:7-16; JTX-1, 17:60-19:35, 19:39-62, 23:13-58. When the patent discusses bacteria, it does so using the same, well known, ***class***-level structural terms as in the claims (e.g., *Bacilli, Mollicutes*). JTX-1, 5:25–30, 7:37-62, *compare* JTX-1, 7:67–8:4 ("at least 7 ***classes***), *with id.* 8:15–19 ("at least 400 different ***species***"), cl. 4. Thus, the specification ***does*** disclose "[1] a representative number of species falling within the scope of the [claimed] genus [and] [2] structural features common to the members of the genus so that one of skill in the art can visualize or recognize the members of the genus." *Ajinomoto Co. v. ITC*, 932 F.3d 1342, 1358 (Fed. Cir. 2019) (internal quotes omitted). Ferring presented no contrary evidence.

Ferring's reliance on *Wyeth* is misplaced. In that case, a "tremendous amount of work and experimentation" would be needed to identify the claimed subset of safe and effective doses, *Wyeth*, 2024 WL 3823006, at *12, *16. Here, Ferring presented ***no*** evidence that ***any*** set of bacterial classes would ***not*** work in the context of the invention; and the evidence presented by UMN showed the opposite. Tr. 96:8-99:19, 192:23-194:24. In *Wyeth*, "nothing in the specification suggest[ed] that the inventors in fact had identified a unit dosage of the specified compounds that

could . . . show the desired therapeutic effect." *Id.* *16. In contrast, the specification here presents clinical data from dozens of patients treated with the claimed compositions. JTX-1, Ex. 4; Tr. 104:11–19; 192:23-194:24. The claims are not about picking ***specific sets of 6*** classes, but rather retaining sufficient diversity, and the specification describes as much in detail, with data. Tr. 96:8-99:19 191:3–9; JTX-1, Fig. 1, Exs. 1-4. Thus, while the *Wyeth* "specification describes an unfinished project," 2024 WL 3823006, at *16, the UMN specification identifies structural properties of the claimed compositions and clinical outcomes of the patients so treated. *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1299 (Fed. Cir. 2014), where the patent claimed IL-12 antibodies but only disclosed one, is inapt for the same reasons.

Second, Ferring claims that "it is undisputed that there is no taxonomic data" regarding the Markush group and relative abundance limitations. Br. 7. But that ***was*** disputed at trial, and Ferring's motion re-raises the same arguments about taxonomic data and the readability of Figure 1 that the jury rejected. While ***Ferring's*** expert testified that "nothing" in Example 1 supports claim 7 and that Figure 1 was "illegible," UMN and Finch presented contrary evidence that the jury was entitled to credit. *Supra*; *see, e.g.*, Tr. 156:18–158:17, 189:2-17, 192:23-194:24. Faced with these facts, Ferring wrongly contends that Dr. Khoruts "admitted that he could not read Figure 1," and Dr. Hamilton "admitted that he could not read even an in-color copy of the figures." Br. 6–7. Here, Ferring points to testimony asking those witnesses to "assign the order level taxonomy from th[e] chart," Tr. 155:20–23 (Khoruts), and "determine the relative abundance of the Clostridia in the donor sample," Tr. 831:24–832:15 (Hamilton). But those are not claim requirements. What Dr. Khoruts ***did*** do—including on cross-examination—was explain how Figure 1 shows the claimed Proteobacteria reduction by referencing column 17's corresponding text. Tr. 156:18–158:17. No further graphical detail was necessary, and the jury was entitled to credit that testimony.

Osseo, 116 F.4th at 1339-40. Ferring's reliance on *Minemyer v. B-Roc Representatives, Inc.*, 695 F. Supp. 2d 797, 804-05 (N.D. Ill. 2009), is inapt because there, the patentee relied on measurements from a non-scaled patent drawing, prohibited as a matter of law.

Third, Ferring attempts to minimize Finch's evidence by incorrectly referring to it as an "inherency theory." Br. 7. Not so. The specification ***explicitly*** discloses the claim elements, *supra*, and taxonomical and clinical data confirming the inventors achieved these results. JTX-1, Fig. 1, 5:25–29, 7:37–8:19, Exs. 1, 4. Testimony confirmed that when the donor screening and fecal processing is applied as described and claimed, the resulting compositions contain at least 6 claimed classes. Tr. 189:2–17, 192:23-194:11, 352:12–22. Ferring suggests this testimony is not "proof." Br. 8. But these patent disclosures, and inventor testimony on how the disclosures would be read by a POSA, are admissible evidence the jury can rely on. The jury must be given "the advantage of every fair and reasonable inference." *Osseo*, 116 F.4th at 1339-40.

Ferring's ***six*** arguments on inherency do not overcome this point. ***First***, Ferring ignores the written description by contending that claim 7 does not require a "healthy donor." Br. 8. But the claims ***do*** require a fecal extract from a donor, and the specification provides instructions on how to identify a donor to obtain that sample to ensure the desired (and claimed) outcome. JTX-1, cl. 4, 17:60–19:35, 19:39–26:54. The inventors explained how the "vigorous donor selection protocol" yields the claimed extracts and results. Tr. 97:1–24, 189:2–17, 192:23-194:24. Contrary to Ferring's suggestion, there is no requirement that the detailed ***description*** of how to achieve the claimed results must also be present in all respects, explicitly, in the claims. *Bone Care Int'l, LLC v. Roxane Lab'ys, Inc.*, 2012 WL 2126896, at *37 (D. Del. June 11, 2012). ***Second***, Ferring suggests, without evidence, that something other than 6 claimed classes of bacteria from donor stool may be transferred instead of what is claimed. Br. 8. This argument is inconsistent with record

evidence, which established that the claimed method transfers "***all***" of the classes, ***including*** the claimed classes when starting with a sample procured as described. Tr. 187:4–7; *id.* 189:2–17 (similar). Unlike the "laundry lists" discussed in *Lipocine*, the specification discloses 10 bacterial classes found in the human gut, and the claims require a composition comprising at least 6 classes to achieve the claimed results. Ferring's ***third*** argument—that processing per every single aspect of the embodiments described in Example 3 or 4 is necessary to achieve a composition with at least 6 of the claimed classes—is also wrong. Br. 9. As Dr. Khoruts explained, key to the invention is that material capable of passing through a 0.5 mm sieve strikes the right balance of purification and retention of bacterial classes, and ***any*** type of filter could be used to achieve that aspect: "a sieve, a strainer, Stomacher bag." Tr. 97:25–99:16; *id.* 189:24-192:13.

Ferring's ***fourth*** argument incorrectly contends "there is no support that any combination" of classes "would be desirable." Br. 9. But the specification reports that the vast majority of the 43 patients treated according to the claims were cured, *see* JTX-1, Tbl. 3, and Ferring has presented no evidence that ***any*** particular set of classes would be ***un***desirable. Ferring's ***fifth*** argument—that the specification does not indicate that a decrease in the relative abundance of Proteobacteria of at least 10% would affect a *C.diff* infection (Br. 10)—is wrong and irrelevant. Ferring does not explain why that must be described in view of the claim language. Regardless, it is: the patent repeatedly explains that a goal of the invention is to treat rCDI., *see, e.g.*, JTX-1, 1:53–3:13, and ties the claimed reduction in Proteobacteria to that treatment, *id.* Fig.1, 16:51–53, 17:22–29; Tr. 156:18–158:12. "[T]he fact that the patients [in Example 4] were cured indicates they no longer have an unhealthy gut," which "[a]bsolutely" means there was at least a 10% reduction in the relative abundance of proteobacteria. Tr. 192:23-194:24 (Sadowsky); JTX-1, 15:21-52. Ferring's ***sixth*** argument is that the extensive evidence of written description is irrelevant, because none of

it was generally known in the art "at the time of the invention." Br. 10–11. That too is wrong. The inventors testified extensively about how they achieved the claim requirements in connection with their conception and reduction to practice of the claimed invention, and their clinical work on the claimed treatment in the 2009–2011 timeframe. Tr. 96:8-99: 24, 188:5–189:17, 192:23-194:24.

IV. The Court Should Deny Ferring's JMOL of No Infringement (UMN Claim 7)

Ferring's request that the Court overturn the jury's verdict of infringement of the UMN patent is based on non-infringement theories Ferring did not present at trial, and should be denied because substantial evidence supports the jury's verdict.[2]

A. Substantial Evidence Supports the Jury's Inducement Verdict

Substantial evidence confirms that Ferring aided, instructed, and otherwise acted with the intent to cause the method steps of claim 7 to be performed by a HCP, and that when those steps are performed, the claimed change in the relative abundance of proteobacteria occurs. Tr. 359:16–361:22 (Benson), 194:15–24 (Sadowsky); PTX-136.66; PTX-922.12; PTX-142.138–139. On JMOL, Ferring does not dispute that HCPs administering REBYOTA directly infringe claim 7, that it knew of the UMN patent, or that it induces HCPs to perform the claimed steps. Br. 12, 14. Instead, Ferring repackages a failed jury instruction argument to assert UMN did not establish inducement of the preamble. Ferring is legally wrong and ignores substantial evidence.

Ferring claims that UMN "failed to adduce any evidence that Ferring encourages [HCPs] to perform '[a] method of decreasing the relative abundance of one or more members of the phylum Proteobacteria to a patient in need thereof.'" Br. 13. But Ferring ***never argued*** during claim construction or otherwise that this preamble language was limiting, so this argument is waived.

[2] UMN need only succeed on either induced or contributory infringement for Ferring's JMOL to fail. *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 851 (Fed. Cir. 2010).

Enovsys LLC v. Nextel Commc'ns, Inc., 614 F.3d 1333, 1345 (Fed. Cir. 2010) (waived post-verdict claim construction). It is also wrong. The preamble is a "characteristic of the method, not an element of the method itself," and is "not an operative step that can be encouraged or not encouraged." *Shire LLC v. Amneal Pharms. LLC*, 2014 WL 2861430, at *6 (D.N.J. June 23, 2014) (rev'd on other grounds). Ferring does not explain why the preamble is a requirement (it is not), and it cannot avoid inducement based on a non-limiting preamble. Its motion should be denied. *See Barry v. Medtronic, Inc.*, 914 F.3d 1310, 1325, 1334–36 (Fed. Cir. 2019) (patentee need not prove non-limiting element to establish infringement).

Even if the preamble were limiting, UMN presented substantial evidence that Ferring encourages HCPs to "decreas[e] the relative abundance of one or more members of the phylum Proteobacteria to a patient in need thereof." JTX-1, cl. 4. There is no dispute REBYOTA achieves this decrease—the jury necessarily so concluded in finding claim 7 infringed, and Ferring does not dispute that health care providers practice that element on JMOL. Tr. 359:16–361:22 (Benson: patients receiving REBYOTA achieve claimed decrease); *id.* 352:23–353:19; 186:12–19, 194:15–24 (Sadowsky); 316:3–12, 318:8–16, 321:11–327:19 (Stollman), 331:23–332:5; JTX-1.18 at 2:54–62; PTX-376.4; PTX-361.

Ferring's contention that it does not encourage the use of REBYOTA for that purpose is at odds with the evidence. Ferring unquestionably intends for health care providers to use REBYOTA to treat rCDI—the jury found as much in connection with finding claims 16 and 21 of the '309 Patent infringed—and substantial evidence supports that finding. *Infra* § VI. That treatment reduces the relative abundance of Proteobacteria—a fact Ferring does not dispute. REBYOTA's label confirms this, instructing HCPs to administer REBYOTA to patients who need their microbiome altered due to their dysbiosis from CDI (PTX-117; PTX-325.2; PTX-604.2), leading

to a decrease in the relative abundance of proteobacteria. *Supra*. Dr. Benson marched through Ferring's documents on an element-by-element basis showing how administration of REBYOTA according to Ferring's instructions achieves the change in Proteobacteria. Tr. 354:9–385:13. That is more than substantial evidence to support induced infringement. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1328 (Fed. Cir. 2021) (vacating JMOL of no inducement).

While Ferring claims that the "mechanism of action of REBYOTA has not been established," Br. 13–14, that is contradicted by substantial record evidence. Ferring ***knew*** that patients receiving REBYOTA in accordance with its instructions achieve the claimed decrease in Proteobacteria, and encouraged HCPs to achieve that result, based on Ferring's clinical results in its FDA submissions and public statements regarding REBYOTA. For example, Ferring's FDA Clinical Trial Report (PTX-136.66) noted that the patient's microbiome post-REBYOTA treatment "was primarily characterized by … decreased Gammaproteobacteria." *See also* PTX-922.12; Tr. 322:5–21; PTX-142.138–39. This is substantial evidence of induced infringement. *See Minn. Mining and Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1305 (Fed. Cir. 2002).

Faced with these facts, Ferring attempts to resurrect an argument the Court already rejected, contending that "providing a label with instructions for administration which, if followed, would infringe" is not sufficient to induce infringement. Br. 13. In Ferring's view, because its label does not specifically mention "Proteobacteria," it cannot induce. At the charge conference, the Court rejected Ferring's proposed jury instruction that included this argument—namely, "[w]here an FDA-approved product label is relevant to providing intent to induce infringement, the label must recommend, encourage, or promote infringement of each and every limitation of the asserted claims," D.I. 473 at 29–30—because "[t]his isn't an ANDA case" and the "jury is permitted to consider the label and other evidence in determining whether or not there's active inducement."

Tr. 1038:10–24. The Court's reasoning is well grounded in law. There is no "label" restriction to prove inducement. *In re Omeprazole*, 258 F. Supp. 2d 221, 234–235 (S.D.N.Y. 2001) ("spectrum of acts" that can establish intent to induce is "broad," not limited to certain documents); *Water Techs. Corp. v. Calco, Ltd*., 850 F.2d 660, 668 (Fed. Cir. 1988) (circumstantial evidence of intent suffices). Rather, inducement can be shown via expert testimony, marketing materials, and press releases, in addition to the label, just as UMN did here. *GlaxoSmithKline*, 7 F.4th at 1335–37.[3]

Moreover, inducement can occur where the drug label "would inevitably lead some physicians to infringe." *Eli Lilly & Co. v. Teva Parenteral Meds., Inc*., 845 F.3d 1357, 1369 (Fed. Cir. 2017). It is undisputed here that the label, consistent with other Ferring documents, would lead HCPs to practice the claimed method. Ferring's cases do not say otherwise. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010) (affirming inducement where the drug label "would inevitably lead some consumers to practice the claimed method."). Ferring knows this: as patentee, Ferring has urged and succeeded in proving inducement based on similar evidence. *Ferring Pharms. Inc. v. Fresenius Kabi USA, LLC*, 645 F. Supp. 3d 335, 379, 380 (D. Del. 2022) (finding inducement where "Defendant knew that performing the steps in the manner directed by its proposed label would cause the claimed reduction in side effects," "***not that the healthcare provider intends for them to occur***"). *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1329 (Fed. Cir. 2009) (Br. 13) is inapplicable: there, the instructions taught a *different set of operative steps* demonstrating an "intent to ***discourage*** infringement."

Finally, as explained below (§ **Error! Reference source not found.**), substantial evidence d

[3] *Biogen Inc. v. Sandoz Inc.*, 2023 WL 7130655 (D. Del. June 29, 2023), is inapposite because there, the patentee relied solely on the label. And unlike in *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015) (an ANDA litigation), Ferring's ***approved*** use encourages infringement, rendering that case distinguishable.

emonstrates that Ferring and Rebiotix copied the UMN inventors' patented work, further demonstrating that Ferring had knowledge of and intent to cause the infringing acts. *See Sonos, Inc. v. D&M Holdings Inc.*, 2017 WL 5633204, at *2 (D. Del. Nov. 21, 2017) (copying evidence relevant to inducement); *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1333 (Fed. Cir. 2016) (similar). The jury's induced infringement verdict is supported by substantial evidence.

B. Substantial Evidence Supports the Jury's Contributory Infringement Verdict

Substantial evidence also supports the jury's verdict of contributory infringement, and Ferring incorrectly argues that UMN purportedly failed to show REBYOTA has "no substantial[ly] non-infringing uses" because Dr. Stollman's testimony was supposedly conclusory and not every REBYOTA treatment is successful. Br. 14–15.

First, Dr. Stollman's testimony on contributory infringement is far from conclusory, and UMN presented substantial evidence that there are no substantial non-infringing uses of REBYOTA. Dr. Stollman provided unrebutted testimony that REBYOTA treats rCDI. Tr. 318:17–327:19. Citing Ferring's clinical trials, REBYOTA label (PTX-117), and advertising, he explained how they show how REBYOTA is to be used by a HCP in a patient needing such treatment, including to repopulate the healthy microbiome. Tr. 321:11–327:24; PTX-142.65 (Ferring FDA presentation: REBYOTA's "clinical efficacy is consistent with microbiome data showing restoration of gut diversity…"). Ferring itself characterized administration of REBYOTA as decreasing levels of proteobacteria. PTX-136.66; PTX-922.12; PTX-142.139. Dr. Benson showed how an HCP administering REBYOTA to a patient results in the claimed decrease in proteobacteria. Tr. 353:3–19, 359:16–363:4, 385:6–386:5. Ferring did not argue or present evidence at trial that there were ***any*** other uses for REBYOTA. Unlike *Yoon Ja Kim v. ConAgra Foods, Inc.*, 465 F.3d 1312 (Fed. Cir. 2006), where there was "***no testimony*** based on the accused

products themselves" to support a finding of infringement, *id.* 1320, here there was substantial evidence of contributory infringement, *i4i*, 598 F.3d at 850-51.

Second, Ferring's argument that there are substantial non-infringing uses because not every treatment results in the relative abundance limitation is at odds with the law: The mere fact that REBYOTA does not always achieve the intended benefit of effectively treating rCDI does not transform the instances of its unsuccessful administration into a substantial non-infringing use. *i4i*, 598 F.3d at 851. Ferring presented no evidence that it encouraged HCPs to do anything with REBYOTA other than achieve the claimed relative abundance limitation. And the jurors heard how (1) Ferring touted the success of REBYOTA (Tr. 290:12–293:2 (Bancke); PTX-1632 at 1:25:55–1:26:16); (2) a hallmark of such success is a decrease in proteobacteria (e.g., Tr. 353:3–19, 359:20–360:4 (Benson), PTX-922.12; PTX-142.139); and (3) an extremely high percentage of patients, 84.75%, achieve the claimed result (Tr. 361:23–363:4 (Benson); PTX-361). Even if trying but failing to infringe ***is*** a non-infringing use, Ferring's argument still fails: "there is no hard and fast numerical threshold in the law" as to what constitutes a "substantial" non-infringing use, and the jury's finding on that issue should not be disturbed. *Midwest Energy Emissions Corp. v. Arthur J. Gallagher & Co.*, 2023 WL 7411710, at *5 (D. Del. Nov. 3, 2023).

Ferring cites two Hatch-Waxman bench opinions that are critically different. In *In re Depomed Pat. Litig.*, 2016 WL 7163647, at *68 (D.N.J. Sept. 30, 2016), the accused drug product had ***multiple approved indications***, including indications that were not claimed. Similarly, in *Sanofi v. Glenmark Pharms. Inc., USA*, 204 F. Supp. 3d 665, 684 (D. Del. 2016), 20% of treatments given with the accused product were off-label. REBYOTA has *one* indication and its *only* approved use is what is claimed. Ferring presented no evidence of any off-label use. "[T]he jury was allowed to consider not only the use's frequency, but also the use's practicality, the invention's

intended purpose, and the intended market." *i4i*, 598 F.3d at 851. Here too, the jury was free to weigh the evidence—including that any alleged "non-infringing use" is contrary to the marketed use (Tr. 327:20–24; PTX-136.66; PTX-922.12; PTX-142.139)—and conclude that 85% success in achieving the claimed reduction (together with the other evidence described above) meant there were no substantial non-infringing uses of REBYOTA. *Grunenthal GmBH v. Alkem Lab'ys Ltd*., 919 F.3d 1333, 1340–41 (Fed. Cir. 2019), does not say otherwise; there, "evidence support[ed] both positions," and the court made "credibility determinations" that the Federal Circuit "s[aw] no reason to disturb." Here too, as substantial evidence supports the jury's verdict.

V. Substantial Evidence Supports the Jury's Verdict of Non-Obviousness

Substantial evidence supports the jury's verdict of non-obviousness for claim 2 of the '080 patent and claim 16 of the '309 patent. At trial, Ferring staked its obviousness defense entirely on the Hlavka reference, which the PTO already considered and which Ferring concedes does not disclose all elements of the claims. Tr. 891:13-893:12 (Britton); JTX-6.4 (listing WO 2011/094027); JTX-4.4 (same). The jury considered all the evidence—including objective indicia of non-obviousness—and rightly concluded that Hlavka did not render the claims obvious. In its JMOL, Ferring improperly makes highly factual arguments and asks the Court to re-weigh the evidence to come to a different conclusion than the jury, falling far short of meeting its "doubly high" burden to overturn the verdict given the clear and convincing standard. *Boehringer*, 320 F.3d at 1353 (Fed. Cir. 2003). In particular, Ferring's inconsistent verdict argument provides no basis for reversing the jury's conclusion on the disputed claims. That argument is waived, but regardless, there is nothing inconsistent about the jury's obviousness conclusions: the invalidated claims are meaningfully distinct from those the jury upheld, and substantial evidence—including of objective indicia, which must "always when present be considered en route to a determination of obviousness," *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983); D.I. 482

§ 9.5—supports and requires upholding the jury's verdict that Hlavka does not render claims with those distinct elements obvious.

A. Ferring Waived Its Inconsistent Verdict Argument

Ferring's argument—that the jury's verdict that claim 2 of the '080 patent and claim 16 of the '309 patent are not obvious is inconsistent with its obviousness verdict on claim 9 of the '080 patent and claim 21 of the '309 patent are obvious—is waived. The jury was properly instructed to assess validity of each claim separately in issuing its general verdict, D.I. 482 at § 9.2, and the jury is presumed to have followed its instructions. *United States v. Hakim*, 344 F.3d 324, 330 (3d Cir. 2003); *Weinar v. Rollform Inc.*, 744 F.2d 797, 811 (Fed. Cir. 1984). Because Ferring did not object to this supposed inconsistency before the jury was discharged, its inconsistent-verdict argument is waived and its obviousness JMOL should be denied. *Frank C. Pollara Grp., LLC v. Ocean View Inv. Holding, LLC*, 784 F.3d 177, 191 (3d Cir. 2015) (inconsistent verdict objection waived when not made "before the jury is excused"); *EMC Corp. v. Zerto, Inc.*, 2016 WL 1291757, at *6 (D. Del. Mar. 31, 2016), *aff'd*, 691 F. App'x 623 (Fed. Cir. 2017) (similar).

B. Substantial Evidence Supports Non-Obviousness of Claim 16 ('309 Patent)

Even if the Court disregards Ferring's waiver, Ferring is wrong on the merits. Ferring contends no reasonable juror could have found claim 16's recitation of a "***cryoprotectant compris[ing] polyethylene glycol***" nonobvious in view of the jury's verdict that claim 21 (reciting an "***antioxidant***") was invalid. *See* Br. 19–20. But the jury's finding that Hlavka does not render obvious claim 21 of the '309 patent is in no way inconsistent with the jury's conclusion regarding claim 16 of the '309 patent and is supported by substantial evidence.

Simply put, a finding that using any antioxidant is obvious does not mean that a narrower claim directed to using a particular type of antioxidant—PEG—is obvious as well, let alone one directed to its use as a cryoprotectant. Ferring's own expert conceded that Hlavka does not

specifically disclose PEG. Tr. 905:14–18. Although Hlavka lists "glycol" as a general class of one of several cryoprotectants, Tr. 878:19–879:3, Dr. Britton admitted there are "***hundreds*** of glycols," including some that can be fatal to humans, Tr. 899:6–18. The jury heard unrebutted evidence that it would ***not*** have been obvious to use PEG, a known laxative, in an enema-delivered pharmaceutical composition designed to treat rCDI, of which a hallmark symptom is diarrhea. *See* Tr. 86:6–87:1, 92:1–11, 629:6–24, PTX-113.2 (Hlavka: "[s]omewhat surprising to me, PEG . . . performed quite well"). Indeed, ***Ferring*** told the PTO, while prosecuting its own patent, that because PEG "is typically used to purge the gut," this "***teaches away*** from using [PEG] with a microbiota restoration therapy composition." PTX-979.535; Tr. 900:14–905:6. In Ferring's words, "[b]ecause of this, it ***would not be obvious*** to combine [PEG with] a microbiota restoration therapy composition." PTX-979.535. Additionally, the jury was presented with substantial evidence of objective indicia of non-obviousness, as discussed below. *Infra* § V.D.

Ferring's attempt to reargue the facts cannot overturn the jury's verdict. Ferring contends that its expert's admissions should be interpreted to mean there are only a "finite number" of glycols, so use of PEG would have been predictable. Br. 20. The jury already rejected Ferring's interpretation of the evidence. Ferring also never says what that "finite" number allegedly is, and it presented no evidence as to how many of these "hundreds" of glycols can be fatal, under what circumstances their lethal effect could be predicted, or why a POSA would have been motivated to select ***any*** glycol considering this potential for lethality, let alone PEG, which is mentioned nowhere in Hlavka. *Knauf Insulation, Inc. v. Rockwool Int'l A/S*, 788 F. App'x 728, 733 (Fed. Cir. 2019) ("broad generic disclosure and a common utility" insufficient for obviousness because "***there must be some reason to select a species from the genus***" (collecting cases)).

Ferring suggests that these statements should be disregarded because they concerned a

reference that is not prior art (Br. 21), but that is not the point. The fact that Ferring stated, in 2015—three years ***after*** the 2012 priority date—that the use of PEG as a cryoprotectant is non-obvious in the context of an FMT preparation is an admission that directly contradicts its position at trial and on JMOL. Regardless, later publications can be relevant to the state of the art, *In re Hogan*, 559 F.2d 595, 605 (C.C.P.A. 1977), and the jury reasonably concluded that skepticism towards use of PEG in microbiota therapy ***after*** the priority date supports non-obviousness as of the priority date. Substantial evidence supports those findings, and JMOL as to claim 16 should be denied.

C. Substantial Evidence Supports the Non-Obviousness of Claim 2 ('080 Patent)

Claim 2 of the '080 Patent, which depends from claim 1, recites the additional limitation "wherein the system protects the fecal bacteria within the pharmaceutical composition from destruction when the sealed container is frozen or exposed to air." JTX-6, cl. 2. Ferring contends that claim 2 of the '080 patent must be obvious because claim 1 (from which invalidated claim 9 depends) includes the requirement that the "pharmaceutical composition is stable during long term storage of the sealed container when frozen," which, coupled with Dr. Britton's testimony that Hlavka's discussion of cryoprotectants, would have bridged the gap between claim 2 and claim 1. Br. 17–18; JTX-6, cl. 1. The jury, however, correctly considered claim 9 separately from claim 2 and appropriately rejected Dr. Britton's testimony to conclude—based on the totality of the evidence including strong objective indicia of non-obviousness—claim 2 was not obvious. Such a highly factual determination cannot properly be disturbed on JMOL.

Ferring's argument ignores the "presumption that distinct claims, particularly an independent claim and its dependent claim, have different scopes." *World Class Tech. Corp. v. Ormco Corp.*, 769 F.3d 1120, 1125 (Fed. Cir. 2014); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (en banc) (similar); D.I. 482 § 6.1. There are two distinct aspects set forth in

independent claim 1 of the '080 Patent: (i) the enema delivery ***system*** and (ii) the pharmaceutical ***composition*** formulated for delivery. JTX-6, cl. 1. Claim 2's additional limitation concerns the former and recites that the "***system*** protects the fecal bacteria" when "frozen or exposed to air." *Id.*, cl. 2. This is absent from claim 1. There is nothing inconsistent in finding a protective system would not have been obvious even if the composition of claim 1 would have been.

Substantial evidence supports this conclusion. Ferring's expert, Dr. Britton, recognized these two distinct aspects of claim 1, explaining that the invention includes a system with a sealed container and tubing, as well as the "other element" of a pharmaceutical composition. Tr. 881:17–24; Tr. 389:15–390:2. And the patent draws these same distinctions, explaining different ways the system can be modified to protect bacteria from freezing or air exposure instead of, or in addition to, modifications to the composition. For example, the patent discloses potential modifications to the delivery vehicle to render it "substantially or completely oxygen free," including by adding a clipped-on oxygen scavenging mechanism, replacing the air in the delivery vehicle with non-reactive gas, or making the container of a material that is "impervious to a gas or to oxygen." JTX-6 at 6:27–7:7, 15:10–14, 19:52–20:15; *id.*, cl. 3. The specification separately discusses substances that may be added to the pharmaceutical composition to stabilize the bacteria in the cold and prevent them from being destroyed during storage and transport, such as "a stabilizing agent or glycerol" and "antioxidants and/or substances such as glycerol." *E.g.*, *id.* 12:39–47, 30:54–57.

Despite its burden to do so, Ferring failed to present any evidence that it would have been obvious to (1) design the ***system*** to protect the fecal bacteria within the composition from destruction when the sealed container is frozen or exposed to air, as required by claim 2, or (2) design such a protective system when the pharmaceutical composition already had these properties. *In re Van Os*, 844 F.3d 1359, 1361 (Fed. Cir. 2017) (rejecting notion that a combination

of two references would have been "intuitive" and explaining such a finding is what "*KSR* warned of and fails to identify any actual *reason* why a skilled artisan would have combined the elements in the manner claimed" (original emphasis)). Ferring cites testimony from Dr. Britton that (i) Hlavka teaches a sterile container, which Ferring claims is sealed, and (ii) that Hlavka teaches addition of a cryoprotectant to the composition to protect it during freezing. *See* Br. 18. The jury was not required to accept Dr. Britton's inference that a sterile container is necessarily sealed. Moreover, whether the container is sealed does not render obvious modifications to the system to protect the fecal bacteria from destruction when the sealed container is "frozen." And, even if Hlavka teaches the addition of a cryoprotectant to the ***composition***, that says nothing about whether it would be obvious to design the claimed ***system***.

Ferring also argues that because claim 2 states "frozen ***or*** exposed to air," Hlavka's teaching regarding the addition of a cryoprotectant is "determinative" of validity without any showing that it would be obvious to design a system that protects the bacteria from air exposure. Br. 19. Not so: by its plain terms, claim 2 requires the claimed system be capable of protecting the bacteria from ***both*** freezing and exposure to air. JTX-6, cl. 2; *cf. Intel Corp. v. Qualcomm Inc.*, 2023 WL 4196901, at *3-*4 (Fed. Cir. June 27, 2023) (rejecting argument "that when a claim recites 'A' or 'B,' prior art disclosing either 'A' or 'B' satisfies the claim"). The '080 Patent provides an enema delivery system that can be stored and transported in conditions that may involve both freezing and exposure to air. *See* Tr. 353:20–354:8; JTX-6 at 4:28–44. And while Ferring points to the addition of an antioxidant to the composition to satisfy claim 2's "exposed to air" element, it does not follow that addition of an antioxidant to the ***composition*** would render obvious modifications to the ***system***. Thus, this is not a case "where the record is critically deficient of the minimum quantum of evidence" in support of the verdict. *Osseo Imaging*, 116 F.4th at 1340.

Rather, the jury was presented with substantial evidence from which it reasonably concluded that Ferring failed to meet its high burden to show invalidity. Ferring's motion should be denied.

D. Objective Indicia Support Non-Obviousness

In addition to the substantial evidence discussed above from which the jury could reasonably conclude that Ferring failed to make a *prima facie* showing of obviousness, the jury was also shown substantial evidence of objective indicia supporting non-obviousness of both disputed claims. It is "presume[d] the jury found that the evidence was sufficient to establish" objective indicia "by a preponderance of the evidence." *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1053 (Fed. Cir. 2016) (en banc).

First, Dr. Borody, the sole inventor of the '080 and '309 patents, was praised ***by Rebiotix*** as a "pioneer" in the field of FMT. PTX-208.1; *Apple*, 839 F.3d at 1053 (competitor's praise is particularly probative). ***Second***, the problem solved by the patents was long-felt. Tr. 315:3–18 (Stollman: long-felt need for "type of system that's claimed in the Finch patents"); Tr. 353:23–354:8 (Benson, similar). Dr. Britton agreed there was a long-felt need for the claimed systems, and while he opined that Hlavka met that need first, the jury was free to, and did, disagree. Tr. 888:7–17. ***Third***, multiple entities licensed or attempted to license the '080 and '309 patents because of their innovations. Tr. 486:16–489:5, 491:19–492:5; PTX-365; PTX-805; PTX-817; PTX-208; PTX-49; PTX-50. ***Fourth***, the '080 and '309 patents were substantially responsible for the significant actual and anticipated commercial success of REBYOTA. Tr. 480:3–17, 496:1–498:4.

Ferring's only response is to challenge this evidence's nexus to the novel aspects of the claims—a question of fact presumed resolved in UMN's favor, *Apple*, 839 F.3d at 1054–55—including because the jury found claim 9 of the '080 and claim 21 of the '309 patent obvious. Br. 22. Specifically, unable to dispute the objective indicia evidence, Ferring repeats its argument that, because the jury found a claim directed to the use of an antioxidant obvious, and heard testimony

that PEG is an antioxidant, the jury should have disregarded the objective indicia evidence. Not so, as explained above, *supra* § V.B, and Ferring offers nothing more than attorney argument to support that unjustified leap. Moreover, nexus—which is "highly fact-dependent" and "within the province of the fact-finder to resolve," *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1331 (Fed. Cir. 2016)—is evident from the objective indicia evidence discussed above. This evidence further bolsters the jury's non-obviousness verdict and Ferring's arguments should be rejected.

VI. The Court Should Deny Ferring's JMOL of No Infringement of Claims 16 and 21 of the '309 Patent

Here, Ferring again improperly attempts to resurrect its failed semantic argument that REBYOTA does not infringe because the REBYOTA label recites "prevention of recurrence of CDI," as opposed to treatment—just as it presented in its unsuccessful pretrial motion. Br. 23–24; D.I. 258 at 24–26; D.I. 421 at 2. Ferring cannot make this argument on JMOL: at trial Ferring ***conceded*** that REBYOTA is a "an FDA-approved safe and effective ***treatment*** for C. diff." Tr. 1248:1–3; *id.* 51:16–24 (similar). And Ferring's expert confirmed that "the point of REBYOTA is to ***treat*** C. diff." Tr. 807:7–9 (Johnson). For these and all the reasons it lost on summary judgment, JMOL is inappropriate. *Grefco, Inc. v. Kewanee Indus., Inc.*, 499 F. Supp. 844, 847 (D. Del. 1980) (defendant "admitted infringement midway through the trial" so issue no longer disputed).

Substantial evidence supports the jury's conclusion that REBYOTA "is in an amount effective for treating recurrence of *C. difficile* infection," and Ferring at best is rearguing the facts. JTX-4.31, cls. 12, 16, 21. Ferring's own descriptions of REBYOTA in its clinical trials and statements to the FDA call it a "treatment." Tr. 290:11–293:2 (Bancke: REBYOTA is effective treatment for rCDI); PTX-117.9 (discussing "treatment success" in clinical trials); PTX-118.3 (describing efficacy of REBYOTA "for the Treatment of Recurrent *Clostridium difficile* Infection"); PTX-136.16; PTX-376.3; PTX-604.6; PTX-1690.2; PTX-1632 at 1:25:55–1:26:16

(Bancke told the FDA that REBYOTA "demonstrated efficacy for the treatment" of rCDI). Ferring cannot distance itself from this sworn testimony by saying these were "unofficial statements," Br. 23–24, they are not, and it failed to object on an evidentiary basis at trial. At most, Ferring's argument goes to the weight of the evidence. Dr. Stollman also presented expert analysis of REBYOTA-related materials prepared by Ferring, opining that REBYOTA "is in an amount effective to treat C. difficile." Tr. 318:8–12; *see also, e.g.*, *id.* 318:17–321:10, 325:16–327:19. Ferring's expert Dr. Johnson agreed. Tr. 807:7–9.

At bottom, Ferring asks the Court to ignore the evidence before the jury that REBYOTA infringes. Br. 23–24. But as the Court previously found (Pretrial Conf. Tr. 50:16–51:2), drug labeling regulations are not dispositive of patent infringement; nor do they trump Ferring's multiple admissions and the substantial evidence concerning what REBYOTA is intended to do and in fact does, *GlaxoSmithKline*, 7 F.4th at 1338. Ferring's motion should be denied.

VII. The Court Should Deny Ferring's JMOL of No Willfulness

If there was ever a case for willful infringement, it is this one, and there is no proper basis to throw out the jury's verdict that Ferring willfully infringed the asserted patents. The evidence of willfulness ran the gamut and was essentially unrebutted: from directly copying the application for certain of the patents in suit and being fully aware of the others, to acknowledging the importance of both the UMN and Borody inventions, to reckless disregard of UMN/Finch's IP rights, the jury had far more than substantial evidence supporting their willfulness verdict. D.I. 482 at § 8 (jury instruction); *SRI Int'l, Inc. v. Cisco Sys., Inc.*, 14 F.4th 1323, 1330 (Fed. Cir. 2021). Ferring's contrary arguments lack merit, as explained below.

A. Substantial Evidence Supports the Jury's Willfulness Verdict (Finch Patents)

The jury's verdict that Ferring willfully infringed the Finch patents is supported by substantial evidence. Before REBYOTA was launched, Ferring indisputably had pre-suit

knowledge of the application to which those patents claim priority, learned of the '309 patent ***as of its issuance*** (pre-litigation), and learned of the '080 patent during this lawsuit, Br. 25; Tr. 344:18–345:2. The jury heard that Ferring believed the Finch patents were important and it needed a license to them. In 2014, Rebiotix contacted Dr. Borody expressing interest in his IP, including the '309 and '080 patents' parent application. PTX-49; PTX-50; Tr. 271:24–272:22, 275:8–9; PTX-208 (Jones 2014 email). Ferring already believed that Dr. Borody was a "pioneer" in the FMT area. PTX-208; *see also* Tr. 588:2–589:4, 964:18–22. Ferring never obtained a license. Rather, when Ferring acquired Rebiotix in 2018, it feared the very litigation loss that has occurred, and so insisted that the founders split fees for patents owned by Finch and UMN if Ferring was "required to take patent licenses or expend money in defending its products against licensing demands." Tr. 570:10–14 (Berman); PTX-56.20–21, 96, 248. Ferring still began selling REBYOTA in early 2023 ***without attempting to design around the claims***, despite knowing the '309 patent and '080 patents had issued before launching REBYOTA, and carried an infringement risk. Tr. 344:18–345:2, 717:20-22; JTX-4.1; JTX-6.1. This failure to "cease its infringing activity or attempt to design around" is well recognized evidence of willfulness. *i4i*, 598 F.3d at 860.

Ferring repeatedly suggests the jury only heard pre-patent evidence of willfulness (Br. 27), but that is incorrect. Ferring knew about the patents, monitored their prosecution (*id.* at 27-28), presented no noninfringement defense for the '080 patent, it has dropped on JMOL the sole noninfringement defense it presented at trial for the '309 patent (that REBYOTA is not "separated from rough particulate matter"—although it is attempting to relitigate on JMOL its "treating" argument that it conceded at trial), and had only one, flawed invalidity argument that the jury rightly rejected for multiple claims. This is more than sufficient evidence to sustain the jury's willfulness verdict, and Ferring's arguments to the contrary are nothing more than an improper

request that the Court reweigh the evidence. *See, e.g.*, *Bd. of Regents, Univ. of Texas Sys. v. Boston Sci. Corp.*, 2022 WL 5241931, at *9 (D. Del. 2022) (denying summary judgment of no post-suit willfulness where defendant knew of the patent, knew it infringed, "and continued to do so anyway"); *see also i4i*, 598 F.3d at 860. Taken together, the totality of the evidence is substantial, and is far more than required to support the jury's verdict. *Broadcom Corp. v. Qualcomm Inc.*, 543 F.3d 683, 700 (Fed. Cir. 2008).

Faced with these facts, Ferring attempts to atomize the evidence (both here and for the UMN patent, *infra*), arguing that certain individual documents do not support willfulness. But the jury was correctly instructed (consistent with well-established law) that willfulness is assessed by considering "all of the circumstances." D.I. 482 § 8. Ferring's motion seeks to reweigh the evidence, which is improper on JMOL.

First, contrary to Ferring's suggestion (regurgitating its pretrial motions, Br. 28), knowledge of the Finch parent patent application ***is*** relevant evidence of willfulness, *C R Bard Inc. v. AngioDynamics, Inc.*, 979 F.3d 1372, 1380 (Fed. Cir. 2020), and Ferring's cited cases are not to the contrary.[4] The merger agreement explicitly identifies the parent application that led to the Finch patents as one of the "[i]dentified [p]atents" that is subject to the cost-sharing provisions. PTX-56.20, 21, 248. Ferring monitored the prosecution of that application (as evidenced by its failed licensing attempts in 2014 and the merger agreement itself), and was aware of the '309

[4] Ferring's cited cases are readily distinguishable from the facts here. *See State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1236 (Fed. Cir. 1985) (defendant "in the dark" about "prosecution" and knew "nothing" about the patent "until it was sued"); *Gustafson, Inc. v. Intersys. Indus. Prods., Inc.*, 897 F.2d 508, 510-11 (Fed. Cir. 1990) (no pre-suit patent knowledge and ***only*** willfulness evidence was failure to investigate); *bioMérieux, S.A. v. Hologic, Inc.*, 2020 WL 759546, at *11 (D. Del. Feb. 7, 2020) (defendant's own product was released ***12 years before*** priority date); *Bayer Healthcare LLC v. Baxalta Inc.*, 989 F.3d 964, 987 (Fed. Cir. 2021) (knowledge of the patent and direct infringement alone not sufficient).

patent once it issued in June 2020 (JTX-4.1) and of the '080 patent during this lawsuit (Tr. 344:18-345:2), both before Ferring marched ahead to launch REBYOTA in early 2023 despite knowing the infringement risk (717:20-22). *See also* Tr. 271:24–22, 275:8–9; PTX-208; PTX-49; PTX-50.

Second, Ferring argues (as it did pretrial) that the merger agreement cannot support the jury's willfulness verdict ***as a matter of law*** because it concerns pre-issuance conduct, and thus must be "particularly egregious." Br. 26. The Court already rejected Ferring's similar "no copying" argument, explaining, "[i]f the evidence shows" Ferring "knew that the [Finch] patent issued and continued to infringe after the patent issued," Ferring's pre-issuance conduct "is relevant to whether the later infringement was willful." Pretrial Conf. Tr. 18:18–24. The law expressly permits fact-finders to consider such pre-patent conduct. *Sunoco Partners Mktg. & Terminals L.P. v. Powder Springs Logistics, LLC*, 624 F. Supp. 3d 473, 483 (D. Del. 2022); *cf. Kaufman Co. v. Lantech, Inc.*, 807 F.2d 970, 978–79 (Fed. Cir. 1986) (affirming willfulness despite "allegedly improper copying [taking] place *before* the patent was issued"). Ferring's sole response—that Finch/UMN must show "particularly egregious" behavior for pre-issuance conduct to be relevant, Br. 26—is wrong. "[W]illfulness requires a jury to find no more than deliberate or intentional infringement." *SRI Int'l*, 14 F.4th at 1330. *Bioverativ Inc. v. CSL Behring LLC*, 2020 WL 1332921, at *2 (D. Del. Mar. 23, 2020) is not to the contrary, and did not announce a "per se" rule that pre-issuance conduct is irrelevant. Rather, the court recognized that "pre-patent conduct may [] be used to support a finding of willfulness," but the facts were not sufficient as the ***only*** pre-patent evidence was "copying" that occurred years ***before*** the priority dates. *Id.* at *2–*3. As discussed above, the facts here are far different, and Ferring cites no reason for the Court to revisit its pretrial rulings.

Third, Ferring suggests that it had a good faith belief of noninfringement (Br. 28-29), relying on a portion of the merger agreement—Rebiotix's purported warranty of no known

infringement of third-party IP—that it never presented to the jury. PTX-56.27 (§ 3.9(b)). But this is just Ferring disagreeing with the jury's weighing of the evidence: Based on the evidence presented to the jury that Ferring ***was*** aware of the Finch patents and ***did*** know that they presented risk, the boilerplate language on which Ferring now relies cannot trump the jury's contrary conclusion. The jury was free to consider all the evidence and conclude that Ferring ***was*** concerned about infringement. The same is true of the freedom to operate searches conducted as part of the merger diligence, particularly given those searches were completed ***before*** the parties agreed to the cost-sharing provision in the final agreement. TX-3960 at 75 (due diligence report); PTX-56.1 (merger agreement). Although Ferring claims that it insisted on the cost-sharing provision because it believed Finch would aggressively litigate its patents, Br. 27, no such evidence was adduced at trial and attorney argument cannot overturn the jury's verdict. *Broadcom*, 543 F.3d at 694.

Finally, Ferring is wrong when it suggests that the only evidence of willfulness was pre-patent evidence. As Ferring's motion admits (at 27-28), it monitored the Finch parent application and knew as soon as the Finch patents issued. *Supra*. More than mere "competitive intelligence," (Ferring's characterization), such monitoring is relevant to willfulness and the totality of the circumstances considered by the jury. *WCM Indus., Inc.*, 721 F. App'x 959, 971 (Fed. Cir. 2018) (monitoring literature showing products marked with "patent pending" is evidence of willfulness).

B. Substantial Evidence Supports the Jury's Willfulness Verdict (UMN Patent)

There is also substantial evidence, and no serious question, that Ferring willfully infringed the UMN patent: Ferring and Rebiotix deliberately copied the UMN patent's disclosures to develop REBYOTA, without making any efforts to design around the claimed inventions. *See, e.g.*, Tr. 344:15–17; 379:14–381:6, 385:6–13 (Benson); 572:15–19 (Berman). And Ferring's own documents explicitly state that REBYOTA's manufacturing process was "derived from" the UMN inventors' Hamilton 2012 paper, (PTX-266.5 (technical proposal), PTX-268.26–27 (request for

proposal), Tr. 749:4–23 (C. Jones)), which is Example 4 of the UMN patent, Tr. 381:14–22 (Benson). Lee Jones even admitted that paper was "[v]ery helpful" to Rebiotix. PTX-47.1; Tr. 701:20–23; PTX-37.

The evidence also showed that Lee Jones disseminated UMN's patented technology to jumpstart REBYOTA's development, and that much of that information—including the UMN provisional patent application—persists in Ferring's files to this day. Tr. 269:13–21, 691:22–692:1, 701:20–23, 703:15–17; 705:18–707:15, 711:17–25 (Jones discussing her dissemination and Rebiotix's use and retention of UMN information to develop REBYOTA); PTX-40.1 (Jones sending Rebiotix consultant UMN's presentation); PTX-42 (UMN presentation); PTX-402.1 (email sending patent application to Jones); PTX-406 (provisional patent application for the UMN patent); PTX-418.2 (Khoruts sending manuscript to Jones); PTX-420 (stage gate report), PTX-421 (MILI program report), PTX-423 (UMN protocol); PTX-1717 (Hamilton 2012 paper). And Rebiotix co-founder Mike Berman confirmed Rebiotix had reviewed the UMN provisional patent at the early stages of developing REBYOTA. Tr. 572:15–573:24 (Berman); PTX-170.1 (February 2012 email indicating Ms. Jones reviewed UMN's "very sciency" patent application). After the UMN patent issued in 2019 (JTX-1.2), Rebiotix superficially attempted to distinguish REBYOTA from the UMN claims because this was "important to avoid potential patent infringement issues," PTX-298, though both Ms. Jones and Mr. Berman confirmed that Ferring actually did nothing to change REBYOTA to avoid UMN's patent rights, Tr. 273:22–274:23, 717:20–718:22 (Jones); 572:11–573:24 (Berman).

The evidence also showed that Ferring intentionally and recklessly pursued commercialization of REBYOTA despite knowing that its conduct presented a substantial risk of infringement, as evidenced by the merger agreement's cost-sharing provisions that applied to any

patents issuing from the UMN parent application. PTX-56.20–21, 96, 248 (merger agreement); Tr. 570:10–14 (Berman). Despite these concerns, Ferring began selling REBYOTA in early 2023 ***without trying to design around the UMN patent claims***. Tr. 263:11–13 (Jones); 295:13–18 (Wannerberger); 544:1–24, 572:11–573:24, 574:8–17 (Berman); 717:20–718:22 (Jones). There is also no dispute that Ferring was aware of the UMN patent itself as of 2019, when it issued. Tr. 344:16–17. That is itself evidence of willfulness, on top of all the other evidence discussed above. *i4i*, 598 F.3d at 860. Taken together, the evidence is substantial and far more than is required to support the jury's finding of willfulness. *Broadcom*, 543 F.3d at 700.

As with the Finch patents, Ferring again wrongly attempts to atomize individual documents rather than looking to the totality of the evidence of willful infringement that the jury considered. Ferring's desire to relitigate its failed pretrial motions and for the Court to re-weigh the evidence are not grounds for JMOL.

First, Ferring repeats its argument the merger agreement is irrelevant as a matter of law because it only identifies the parent application, not the patent. Br. 28. As explained above, knowledge of the patent application ***is*** relevant evidence of willfulness. *C R Bard*, 979 F.3d at 1380. This is particularly true where, as here, there is substantial evidence that Ferring copied UMN's patented invention. *Supra*. Moreover, the parent application had draft claim limitations that mirrored those that ultimately issued. *Compare* JTX-1 ('914 patent), *with* TX-3768 (discussing U.S. Patent Application No. 15/173,134). And, as the evidence confirmed, Ferring monitored the prosecution of that application, and as such, was aware of the patent once it issued. Tr. 344:16–17; PTX-170 (L. Jones: application is "very sciency").

Second, Ferring again argues (as it did pretrial) that this evidence is insufficient because it concerns pre-patent conduct, and thus must be "particularly egregious." Br. 28–29. The Court

rejected this argument for the UMN patent too, explaining that "whether Ferring's side copied aspects of the technology claimed by the UMN patents before those patents issued . . . might have some bearing on whether infringement that occurred after the patents issued was willful." Pretrial Conf. Tr. 18:9–17; § VII.A, *supra*.[5] Ferring's pre-patent conduct is especially relevant here, where Ferring knew it was copying material that was patented. Tr. 273:22–274:23 (L. Jones), 749:4–23 (C. Jones), PTX-298.1, 2 (Jones 2020 email), PTX-266.5 (technical proposal), PTX-268.26–27 (request for proposal). Ferring identifies no reason for the Court to revisit its pretrial rulings, and regardless, Ferring's pre-issuance actions *were* particularly egregious, as described in detail above. Ferring never wavered from its plan to copy UMN's patented technology, without ever modifying its product to avoid those patent rights, both before and after the patent issued. This is far more than substantial evidence supporting the jury's willful infringement verdict. *Knorr-Bremse*, 383 F.3d at 1342.

Third, Ferring's argument that it had a good-faith basis of noninfringement (Br. 28–29) is essentially identical here as for the Finch patents, and it is equally unavailing. *Supra* (discussing purported warranty). While Ferring attempts to bolster its no-willfulness defense by pointing to a merger-diligence email as supposedly "corroborat[ing]" evidence that it had a subjective belief it did not infringe the UMN patent (an attempt it does not make for the Finch patents), the jury was free to consider the "noninfringement" position set forth in the email as part of the totality of the circumstances and reject it. Br. 29. And it did: this merger-diligence email tracks the Ferring's "not capable of passing through a 0.5 mm sieve" defense, *see, e.g.*, Tr. 788:5–14). Even Ferring

[5] *Gustafson* is inapposite. Br. 29. There, the Court reaffirmed that the proper inquiry is to look to the totality of the circumstances to see if a finding of willfulness is supported. *Gustafson, Inc. v. Intersys. Indus. Prods., Inc.*, 897 F.2d 508, 510 (Fed. Cir. 1990). Unlike here, the ***only*** willfulness evidence was defendant's failure to investigate, despite its undisputed lack of pre-suit knowledge of the patent, which is plainly distinguishable from this case. *Id.* at 510-11.

recognizes the defense lacks merit—despite it indiscriminately challenging nearly every aspect of the jury's verdict, even Ferring has abandoned this defense on JMOL.

Finally, as it did in pre-trial motions, Ferring disputes whether ***individual*** documents show copying, rather than looking at the totality of the evidence. Br. 30-33. As an initial matter, the Court decided this gating evidentiary dispute pre-trial. *Supra*. And the jury received more than substantial evidence showing that these documents support UMN's copying allegations, including because they include valuable information about the UMN patented technology, which Ferring in turn relied on in connection with developing REBYOTA. Tr. 265:8–267:8, 269:18–270:5 (Jones); 379:14–384:18, 419:22–420:1 (Benson); PTX-42 (UMN MILI presentation); PTX-420 (confidential stage gate report). These documents are relevant evidence of Ferring's access to UMN's technology and copying of UMN's invention, and Ferring did not object to their admission at trial. As explained below, Ferring's arguments that these documents are not relevant evidence of copying are contradicted by the documents themselves, and constitute nothing more than disagreements with the jury's findings of fact.

Ferring first targets the documents found in Ms. Jones's possession during this litigation, including a UMN MILI presentation (the "powerpoint") and stage gate report, arguing (incorrectly) that these documents lack technical information. Br. 30-31. The stage gate document discusses "potential novelty" of the UMN inventors' innovation, including both a donor selection and processing protocol, as well as the "molecular 'fingerprint' of the donor microbiota," PTX-420.5, all of which relates to the technology of claim 7. The MILI presentation, likewise, contains technical details relevant to claim 7, including that it contains "10 different classes of bacteria," as well as discussion of possible patent claims, PTX-42.7, 10–12; *see also* Tr. 383:25–384:18. That "***is*** evidence of copying." *Medtronic, Inc. v. Teleflex Innovations S.a.r.l.*, 70 F.4th 1331, 1340 (Fed.

Cir. 2023); *Liqwd, Inc. v. L'Oreal USA, Inc.*, 941 F.3d 1133, 1138 (Fed. Cir. 2019) ("access to *published articles* about a patented method" relevant evidence of copying (original emphasis)).

Ferring next takes aim at its processing protocol, which, as shown at trial, was specifically "derived from" the Hamilton 2012 paper written by the UMN inventors and includes the patented protocol. PTX-401, PTX-266.5 (technical proposal), PTX-268.26–27 (request for proposal); Tr. 381:14–22 (Benson), 749:4–23 (C. Jones). Faced with its own admissions, Ferring contends that willfulness requires that Rebiotix used an "exact copy" of the disclosed process, yet its own proposal somehow "highlights the [purported] differences" between the UMN patents and REBYOTA because it also cites to other papers. Br. 32. Willfulness does not require an "exact copy," *Eaton Corp. v. Parker-Hannifin Corp.*, 292 F. Supp. 2d 555, 569–70 (D. Del. 2003). The focus is on "substantial similarity" and access, *Medtronic*, 70 F.4th at 1340, and the jury received overwhelming evidence that Ferring had access to the information in the patents and used it to develop REBYOTA. Tr. 381:14–22, 707:20–708:19; PTX-266.5 (Rebiotix's process was "derived from" Hamilton 2012); PTX-401 (UMN process protocol); PTX-422 (UMN patent application).

Moreover, the purported "differences" Ferring highlights between Hamilton 2012 (included verbatim in Example 4 of the patent) and the REBYOTA process are "not so significant as to preclude substantial similarity and the corresponding inference that [Ferring] copied." *Medtronic*, 70 F.4th at 1341. For instance, both were aimed at achieving a uniform suspension—one used a "mixer," one used "vortexing." PTX-266.8. Both had the goal of cryopreserving the product. *Id.* That the process for REBYOTA did not include every single step from Hamilton 2012 (*e.g.*, centrifugation) does not defeat the substantial similarity between the two processes—particularly where, as here, supposed differences that Ferring points to (e.g., centrifugation) are not required by the claims. Pretrial Conf. Tr. 50:2–10; D.I. 145 (Markman Order); D.I. 148

(Markman Tr.) at 110:7–13. Ferring's sugestion that the Court should override the jury's conclusions by pointing to disputed testimony from its own witnesses showing alleged differences, Br. 32-33—differences the jury was not required to accept—leaves no doubt about Ferring's misunderstanding of the proper role of JMOL in a jury case.

VIII. The Court Should Deny Ferring's Damages JMOL

Ferring's attacks on the jury's damages award—which awarded Finch and UMN less than half of what they sought—consist largely of rehashed *Daubert* arguments or Ferring's preferred view of the evidence, which the Court and jury considered and rejected. UMN presented extensive evidence in support of its damages analysis, including support for an upfront payment. Based on the evidence and unobjected-to instructions, the jury awarded an upfront payment of $25 million and a running royalty of $815,061 through trial. None of Ferring's arguments support setting aside the jury's considered damages award, and its JMOL should be denied. *See Green Mountain Glass v. Saint-Gobain Containers*, 300 F. Supp. 3d 610, 618 (D. Del. 2018).

A. Ferring's "Novel Aspects" Argument Ignores Evidence and Misstates the Law

Ferring contends that there is not substantial evidence that the novel aspects of the UMN and Finch patents provide value to REBYOTA. Br. 33–36. Although Ferring's argument is largely based on *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1339 (Fed. Cir. 2015), the holding in that case ***rejected*** the very argument Ferring makes here.[6] Ferring contends that a claim's "novel elements" must be valued separately from its "conventional elements." Br. 34–35. Apotex made the same argument, and the Federal Circuit rejected it, explaining that when "a patent that combines 'old elements,' removing the value of all of those elements," as Ferring seeks to do,

[6] Ferring's other cases are inapt. *Aqua Shield v. Inter Pool*, 774 F.3d 766, 772 (Fed. Cir. 2014) (error to cap royalty at profits); *Omega Patents v. CalAmp*, 13 F.4th 1361, 1376–78 (Fed. Cir. 2021) (new damages trial with generic license testimony); *Ericcson v. D-Link*, 773 F.3d 1201, 1226–27 (Fed. Cir. 2014) (license-based royalty proper for "multi-component products").

"would mean that nothing would remain." *AstraZeneca*, 782 F.3d at 1339. Thus, "[i]t is not the case that the value of all conventional elements must be subtracted from the value of the patented invention as a whole when assessing damages." *Id.* 1339. Rather, "the question is how much new value is created by the novel combination, beyond the value conferred by the conventional elements alone." *Id.* Ferring's argument is thus foreclosed by the very precedent on which it relies. *See id.* (no reason to exclude value of conventional active ingredient when calculating damages); *Solutran v. U.S. Bancorp*, 2019 WL 405513, at *14–18 (D. Minn. Jan. 18, 2019) (similar).

Ferring nonetheless proceeds to parse the infringed claims into purportedly "conventional" and "non-conventional" elements, and then contends that (i) the Borody patents have ***no*** benefits over non-conventional elements because the antioxidant claims were found obvious; (ii) Mr. Malackowski did not separately value using PEG in claim 16 of the '309 patent or value of the Hlavka patent; and (iii) there is no evidence that the UMN patent claims any benefits over the prior art. Br. 33–36. Even if the court considers this legally flawed argument, substantial evidence supports the jury's conclusion that the claimed combinations provide significant value beyond any conventional elements "standing alone." *See Astrazeneca*, 782 F.3d at 1338.

Regarding the Borody patents, Ferring relies on Dr. Benson's high-level description of the claims, Br. 34, but ignores his further testimony and record evidence focusing on PEG's benefits to REBYOTA and REBYOTA's need to protect bacteria from freezing and air exposure, which go beyond cryoprotectants and antioxidants generally. *Supra* § V.B, C; Tr. 399:4–6 (PEG's "function is a cryoprotectant"); PTX-113.2 (Hlavka expressing surprise that PEG "performed quite well"); PTX-979.535 (Rebiotix telling PTO about unexpected utility of PEG). For claim 2 of the '080 patent, Ferring's FDA submissions described the enema bag system as an "optimal primary enclosure," and that the "bag … ***was selected specifically because [it] resists the loss of water***

vapor and transmission of oxygen." Tr. 391:16–392:9; *see also* PTX-139.33, -0043; PTX-929.7, -23. This is a significant benefit, as "***many of the fecal bacteria are quite sensitive to oxygen. So it's important that that bag prevent transmission of oxygen***." Tr. 391:16–392:9. In addition to hearing from Dr. Benson and seeing REBYOTA's own FDA submission touting that feature, Lee Jones testified that REBYOTA's bag was self-contained, so there was no oxygen that got in, allowing REBYOTA to not use nitrogen gas. *Id.* 656:14–21.

Ferring's assertion that Finch and UMN were required to independently value the PEG element of claim 16 of the '309 patent or the Hlavka patent are likewise unavailing. The *Georgia-Pacific* factors, which the jury considered, appropriately address the qualitative impact of improvements over the prior art. Dr. Benson provided extensive evidence demonstrating how REBYOTA meets every element (*id.* 355:22-386:5) to reach the conclusions that this patented method critically contributed to REBYOTA (*id.* 402:6-16), there were no value-added components to REBYOTA that did not include the claimed elements[7] (*id.* 400:17-401:7), and there were no non-infringing alternatives—which Ferring's own expert, Mr. Kidder, confirmed (*id.* 968:6-24). Mr. Malackowski explained that "what matters to [him] is the innovation here and what is the alternative to that innovation, which is none" (*id.* 514:12-16). The jury also heard evidence specific to the inclusion of PEG in the claims. *Id.* 285:23-286:21, 399:2-6, 753:3-14, 755:2-7. Ferring witness Courtney Jones testified that the use of PEG was necessary for REBYOTA. *Id.* 737:7-738:1. And REBYOTA's BLA touted that PEG importantly "provided the best viability [for REBYOTA] when compared to other commonly used cryoprotectants." PTX-217.11-12. Further,

[7] Ferring wrongly suggests a conflict between Mr. Malackowski and Dr. Benson's testimony. D.I. 502 36. But Mr. Malackowski's testimony focused on the importance of the patents to REBYOTA (Tr. 511:12–513:1), while Dr. Benson was focused on whether "it would be impossible to develop ***any product in this field*** without" the patents (*id.* at 418:6–16).

with respect to the Hlavka patent, Mr. Malackowski explained that "if there [are] elements that are discussed within the Hlavka patent but they are combined in new, innovative ways in the Finch patents and the patent office, who saw the Hlavka patent, still granted these claims, then you'll see some overlap" and that "what you need to value is the totality of the claim that's being asserted here" (*id.* 514:3–11). That is precisely what the law requires, and what Mr. Malackowski did. *See Astrazeneca*, 782 F.3d at 1338–39; *Idenix Pharms. LLC v. Gilead Scis., Inc.*, 2018 WL 922125, at *6-8 (D. Del. Feb. 16, 2018).

Regarding the UMN patent, Ferring did not even allege a prior-art based defense, yet it attempts to reduce the claims to the "capable of passing through a 0.5 mm sieve" limitation. This ignores the combination of the claim elements, including the requirement for six of ten specified classes of bacteria, 10% reduction in the relative abundance of Proteobacteria, and increased fecal microbiota diversity. JTX-1 cls. 4, 7. And as Dr. Khoruts explained, the combination of these elements allowed for the "manufacturing process" for an FMT treatment "to get to the point of having a standardized product that then could be shipped to healthcare providers." Tr. 97:1–5; *see also id.* 100:18–20; 182:13–18. This novel method included "separat[ing] the bacteria from the … nonliving material" in a "speedy" manner so that the bacteria are not "exposed to oxygen." *Id.* 97:25–98:8. The patented invention also required the material be capable of passing through a ".5 millimeter pore"—"[n]ot too big, not too small"—which struck the right "balance" to prevent the "los[s of] some groups of bacteria" that feed on the "nonliving particles." *Id.* 98:9–99:2. Accordingly, substantial evidence supports the jury's conclusion that the claimed combination provides significant value. Ferring's argument lacks merit and its motion should be denied.

B. Ferring Rehashes Its Rejected *Daubert* Arguments

Ferring next argues that Mr. Malackowski's reliance on the Seres agreement was improper because that agreement was not comparable. Br. 36–39. The Court already rejected these

arguments at the *Daubert* stage (*e.g.*, Nestle-Seres is not comparable because it is not a bare patent license or does not list the licensed patents), finding that Mr. Malackowski "sufficiently explain[ed] the basis for his opinion" that the hypothetical license "includes an upfront fee plus ongoing payments" and that "the cited cases do not say that such a structure is impermissible," and further ruling that Mr. Malackowski had "assessed the comparability of the licenses and Ferring's critiques are fact issues best addressed by cross-examination." D.I. 421 3–4. Ferring raised no objection to Mr. Malackowski's testimony at trial, or the admissibility of any agreement, including Seres. Tr. 489:6–491:15, 502:16–506:2. Ferring, therefore, has waived this argument, and JMOL is not the proper vehicle for rehashing unsuccessful *Daubert* arguments. Its motion should be denied. *See United States v. Paulus*, 894 F.3d 267, 278 (6th Cir. 2018) (denying JMOL based on repackaged *Daubert* arguments); *Rembrandt Wireless v. Samsung*, 2016 WL 362540, at *4 (E.D. Tex. Jan. 29, 2016) (similar). In any event, as explained below, substantial evidence supports the jury's damages verdict, including extensive evidence of the comparability of the Seres agreement.

C. Substantial Evidence Supports the Jury's Damages Award

Ferring's suggestion that insufficient evidence supports the jury's damages award (Br. 43) ignores large quantities of trial evidence supporting that award. Both parties' damages experts relied on licenses related to FMT technology, and applied the *Georgia-Pacific* factors to arrive at their damages opinions. Finch and UMN also presented technical expert testimony to support its damages analysis. Tr. 400:17–401:7, 402:6–16 (Dr. Benson: asserted patents "critically contribute to the function of" REBYOTA and that he did not "find any value-added components to REBYOTA that does not include the claimed elements of the patents."). From Dr. Benson's testimony, the testimony of other witnesses, and his consideration of all of the *Georgia-Pacific* factors, among other evidence, Mr. Malackowski concluded that the UMN and Finch patents "contribute critically to REBYOTA's composition," "represent significant improvements in the

field," "are substantially responsible for the success of the Ferring product," "make REBYOTA an effective, viable product," and "there are no alternative ways for them to make a commercially successful product." *Id.* 480:1–17. Mr. Malackowski also noted that Ferring itself shared the view that prior to UMN inventions, the "standard of care or antibiotics for this disease ha[d] its limitations," "the market[] need[ed] a new solution," and REBYOTA, "the [product] that's practicing the inventions here[,] is an effective solution." *Id.* 481:19–482:4; PTX-739A.37.

The jury also heard significant evidence supporting the upfront payment/running royalty structure. Mr. Malackowski testified that "upfront payments" are "[v]ery common" and present "in virtually all of the agreements that [he had] seen in the industry." Tr. 475:9–14, 502:18–503:3. This included Finch's agreements and offers for the patents-in-suit (*e.g.*, Takeda and Ironwood), as well as third-party agreements that Finch concluded included comparable technology (*e.g.*, Seres). Tr. 482:23–483:6, 484:22–485:9; PTX-365.35; PTX-817.2; PTX-366.85. Mr. Malackowski also explained his conclusion as to why the Seres agreement was the most comparable, Tr. 489:6–13, 490:14–491:15, and how he apportioned the amounts in that license to isolate the value of the patented technology. Mr. Malackowski removed the "quarter-billion to 440 million of milestone payments" under the license (*id.* 532:5–9) and applied a 50% apportionment to the $175 million upfront payment based on Finch's own agreements to remove the value of know-how and other non-patent value. *Id.* 503:17–504:6, 532:10–11; PTX-365.39–40; PTX-805.13. Applying this Finch-license factor to the Seres license was appropriate, particularly given that Finch had reviewed Seres patents and concluded that its own patents were more valuable. Tr. 439:9–15; PTX-1731. Moreover, Mr. Burgess, Finch's former co-founder and VP of Innovation, testified that Finch would have sought higher upfront payments than in its license with Takeda and the Ironwood offer if it had been negotiating with a competitor, and that the monetary value in

those licenses was lower than it otherwise would have been due to Finch's financial condition. Tr. 435:25–437:14, 488:17–489:5.

Mr. Malackowski then further reduced the upfront payment from $87.5 million to $50 million based on "the balance of the *Georgia-Pacific* Factors." *Id.* 504:21–505:6. Ferring is incorrect that Mr. Malackowski used the upfront payment in the Merger Agreement as his basis for apportionment. Br. 38–39. Instead, Mr. Malackowski considered all the *Georgia-Pacific* Factors in his analysis (Tr. 479:6–18), and the benchmarks he discussed at length in his prior testimony, such as the competition between the parties, Ferring's first mover advantage, and Ferring's market entry forcing Finch from the market despite Finch spending $92.9 million in research and development costs (*id.* 498:22–500:22). As Mr. Malackowski stated, the competition between the parties "should further increase the upfront payment." *Id.* 504:21–505:6. However, Mr. Malackowski did not increase the upfront payment because he accounted for "what [he] thought would be Ferring's argument of they have their own market benchmark of what they paid for similar technology of 51 million."[8] *Id.* And "giving what [Mr. Malackowski] think[s] is ***the benefit of the doubt*** to Ferring, [he] would cut the upfront payment back again to 50 million." *Id.* (emphasis added). For the running royalty, Mr. Malackowski reached 30% by considering the Seres agreement, Ferring's contributions under *Georgia-Pacific* factor 13, an industry study, and the assumption that the patents are valid and infringed. *Id.* 505:7–20.

Ferring's expert, by contrast, testified that there would be no upfront payment at all, and that the running royalty would be 5.5%. Tr. 920:20–921:8. Although he believed upfront payments were inappropriate, on cross, he admitted that a study he relied on reported that "***75%*** of all bare

[8] The upfront payment was only a portion of the $128 million anticipated sales price of Rebiotix, but Mr. Malackowski excluded those additional milestone payments to account for the licensee's contributions. Tr. 485:10–16, 501:5–19.

patent licenses and patent plus know-how licenses ***included upfront payments***" and that in a Licensing Executives Society presentation he relied on, "***80% of the licenses … had upfront payments.***" *Id.* 952:4–19, 960:19–963:20.

The jury considered this and other evidence, and arrived at a damages award in between what both experts proposed: a $25 million upfront payment and a running royalty of $815,061 (approximately a 5.5% royalty). The jury's upfront payment is well within the range of upfront payments in the comparable licenses (which ranged from $10 million to $175 million). Ferring now argues that the jury should not have awarded an upfront payment based on arguments that the jury heard, and reasonably rejected. Ferring's desire that the jury adopted its position in full is not grounds for JMOL, and Ferring's motion seeking to overturn the jury's carefully considered damages decision should be denied, for multiple reasons. *Shopify Inc. v. Express Mobile, Inc.*, 2024 WL 2260900, at *14–17 (D. Del. May 17, 2024).

First, Ferring incorrectly argues that the Seres agreement is not comparable because it contends it is a product collaboration agreement, as opposed to a bare patent license, and does not list the specific licensed patents. Br. 36–37, 39–40. Ferring, however, does not argue that other so-called "product-collaboration" licenses (e.g., Takeda and OpenBiome) lack comparability, including the license its own expert relied on between UMN and Finch: just like the Seres agreement, the UMN-Finch agreement on which Ferring's own expert relied heavily included an upfront payment, milestone payments, and a running royalty, albeit at a rate lower than would be charged to a competitor because of the close collaboration between UMN and Finch. PTX-823.3; Tr. 227:13–19, 229:16–230:5, 483:7–16. Ferring also cites no case precluding reliance on "product collaboration" licenses for purposes of the hypothetical negotiation. Indeed, the Federal Circuit has "never required identity of circumstances." *VirnetX v. Cisco*, 767 F.3d 1308, 1330–31 (Fed.

Cir. 2014); *ViaTech v. Adobe*, 2023 WL 5975219, at *7 (D. Del. Sept. 14, 2023) (permitting expert testimony on license comparability despite fact that it "is not a patent license"). UMN and Finch established that the Seres agreement meets the baseline comparability requirements, acknowledged that the Seres agreement differed from the hypothetical negotiation, and provided a reliable apportionment methodology to account for those differences, as explained above. *Puma Biotech. v. AstraZeneca*, 2024 WL 1157120, at *21 (D. Del. Mar. 18, 2024); *see also Bio-Rad Laby's v. 10X Genomics*, 967 F.3d 1353, 1374 (Fed. Cir. 2020) (no abuse discretion in allowing expert to testify where "Mr. Malackowski had met a showing of 'baseline comparability'").

"The degree of comparability" of a license is a "factual issue[]" for the jury to resolve. *ActiveVideo v. Verizon*, 694 F.3d 1312, 1333 (Fed. Cir. 2012); *see also Bio-Rad*, 967 F.3d at 1374. To engage in this analysis, the jury was instructed to consider several factors in assessing the comparability of licenses in arriving at its verdict. Tr. 1127:19–1128:4. Ferring, however, claims that it is "impossible" to account for the differences between the Seres agreement and the hypothetical negotiation because the licensed patents are not specified. Ferring made this same argument to the jury. Tr. 924:12–926:8, 1237:14–1238:21. Ferring's JMOL takes this argument further, raising potential differences between Seres' product and the asserted patents that it claims have bearing on comparability. Ferring, however, presented no evidence on this issue to the jury, and it cannot make this argument in post-trial briefing for the first time. *See WBIP*, 829 F.3d at 1338. Regardless, Finch presented evidence that the Seres agreement covered an "FMT product intended to treat [rCDI]"—just as REBYOTA is an FMT product intended to treat rCDI. Tr. 401:18–402:5. Ferring acknowledges that Finch understood that the Seres agreement was an important benchmark for its own products, but ignores that Finch had analyzed Seres' patents, and concluded that its own patents were more valuable than Seres. *Id.* 438:6–439:15. Substantial

evidence supports the jury's rejection of Ferring's arguments.

Second, Ferring contends that ***none*** of the upfront payment in the Seres agreement is attributable to patent rights based on its expert's contested interpretation of the Seres agreement. Br. 36–37. Ferring presented this precise argument at trial, but, as Mr. Malackowski explained, the Seres agreement makes clear that the "upfront payment of $175 million" is paid as "partial consideration" for the "license under the intellectual property" rights granted in the agreement. Tr. 490:14–491:6; PTX-366.40, -85. When its expert was faced with the plain language of the agreement itself, he was forced to admit the same. Tr. 924:17–925:1, 943:12–949:2. Ferring's brief attempts to avoid this clear admission, and the plain language of the license, by arguing that the license related only to "commercialization," Br. 40, but that is not what the license says. PTX-366.85. Ferring's resort to extrinsic evidence, *i.e.*, Seres' SEC filing related to how it would account for the upfront payment, does not change the language of the agreement (PTX-366.152). *Takeda v. Mylan*, 967 F.3d 1339, 1345–46 (Fed. Cir. 2020) ("extrinsic evidence may not be used to … vary the terms of the contract"). The jury heard this evidence.

Third, Ferring claims that Mr. Malackowski testified that the entire $175 million upfront payment in the Seres agreement "is attributable to intellectual property rights." Br. 36–37, 41–42. This was not his testimony, and Mr. Malackowski apportioned from $175 million down to $50 million—and the jury apportioned still further, down to $25 million. The Seres agreement itself says what the upfront payment is for—"***partial consideration***" for the licenses and rights granted, which included patent rights and other IP. PTX-366.85.

Fourth, Ferring contends that Mr. Malackowski's upfront payment apportionment is flawed and that the jury improperly ignored Ferring's desire not to pay a lump sum. As an initial matter, the jury was instructed that the royalty should "not simply [be] a royalty that either party

would have preferred," and Ferring did not object to this instruction. D.I. 482 at 38. Moreover, Ferring raises the same critiques that it did on *Daubert* and at trial, and those arguments fare no better now. *Compare* D.I. 492 at 56:19–57:6, *with* Br. 36. The Court, however, rejected Ferring's argument, as explained in § VIII.B., *supra*, and the jury heard Ferring's criticisms and cross-examination of Mr. Malackowski and likewise rejected Ferring's argument. Ferring also presumes that the jury relied exclusively on the Seres agreement, even though there were several comparable licenses in the record with a range of upfront payments and running royalties. The jury also heard evidence regarding adjustments that could be made to these agreements in the hypothetical negotiation. Tr. 435:25–437:14, 439:9–15, 488:17–489:5. The totality of the evidence supports the jury's award of a $25 million upfront payment. *See Fujifilm v. Benun*, 605 F.3d 1366, 1372–73 (Fed. Cir. 2010) (plaintiff presented evidence sufficient to support a damages verdict "even larger" that what "jury awarded"); *Transocean v. Maersk*, 699 F.3d 1340, 1358 (Fed. Cir. 2012) (reversing grant of JMOL where substantial evidence supported jury's "upfront licensing fee," noting that "[w]e may well not have awarded such a high royalty, but that decision is not ours to make").

Finally, Ferring claims that the jury was "confuse[d]" into awarding an upfront payment because Mr. Malackowski suggested the Seres agreement and the Ironwood offer were bare patent licenses, as opposed to including additional rights. *Id.* 41–42. There was no confusion on this point. As Ferring itself notes, Mr. Malackowski agreed that these licenses were not bare patent licenses, which the documentary evidence likewise confirms. *Id.* 39–40. Moreover, the Ironwood offer undisputedly included the patents-in-suit, and Finch explained that the offer was unacceptably low. Tr. 436:25–437:25. The jury thus awarded an upfront payment that was well within the range of upfront payments in the record. Ferring's motion for JMOL should be denied.

D. No Remittitur of the Upfront Payment Should Be Granted

Ferring's argument for remittitur is wholly conclusory and can be denied for that reason

alone. *Torres v. City of Chicago*, 2016 WL 4158914, at *23 (N.D. Ill. Aug. 5, 2016); *see also* D. Del. L.R. 7.1.3(c)(2). Even if considered, the jury's upfront payment is neither excessive nor unsupported, as explained above. Indeed, the jury's award (less than half of what was sought) is a fraction of Ferring's $2 billion projected sales of REBYOTA and still allows Ferring to earn a substantial margin on sales of REBYOTA. *Union Carbide Chems. v. Shell*, 2004 WL 1305849, at *15 (D. Del. June 9, 2004) (denying remittitur where jury awarded 33% royalty and plaintiff sought 50%). Neither of Ferring's cases support remittitur here. *See Boyce v. Edis*, 224 F. Supp. 2d 814, 818–19 (D. Del. 2002) (remittitur of 50% of award for loss of consortium damages because wife did not have to provide burdensome care); *Rex Med. v. Intuitive Surgical*, 2023 WL 6142254, *8–9, *11 (D. Del. Sept. 20, 2023) (remitting damages where witness admittedly could not assign value to asserted patent in license). Ferring's request for remittitur should be denied.

E. Damages Should Not Be Reduced If Only One Set of Patents Is Valid/Infringed

There is no reason to reverse the jury's validity and infringement findings, as explained *supra*. But even if the Court disagrees and only the Finch Patents or the UMN Patent is valid and infringed, Ferring has forfeited these grounds. Although the "general rule" is that if there is a "single verdict on damages, without breaking down damages attributable to each patent," a new trial is required, there is good "reason to depart from this general rule" here. *Verizon v. Vonage Holdings*, 503 F.3d 1295, 1310 (Fed. Cir. 2007); *SK Hynix v. Rambus*, 2013 WL 1915865, at *15 (N.D. Cal. May 8, 2013). The jury instructions and verdict form requested that the jury award damages if any claim from any patent was valid and infringed, D.I. 480 at 5; D.I. 482 at 38. Ferring "did not request an instruction giving the jury a method for calculating damages on a [patent]-by-[patent] basis." *SK Hynix*, 2013 WL 1915862, at *15. As a result, Ferring has forfeited its argument that damages should be reduced if only the Finch patents or the UMN patent is valid and infringed. *Alfred E. Mann Found. v. Cochlear Corp.*, 2018 WL 6190604, at *12 (C.D. Cal. Nov. 4, 2018)

("Courts do not 'allow litigants to play procedural brinkmanship with the jury system and take advantage of uncertainties they could well have avoided.'").

Regardless, substantial evidence supports the full award. Dr. Benson opined that "both the University of Minnesota patents and the Finch patents are really necessary and they critically contribute to the function of the REBYOTA product." Tr. 402:6–16. Mr. Burgess also testified that when licensing the UMN and Finch patents, Finch did not "charge a separate royalty for each patent." *Id.* 434:8–10. Relying on this testimony, Mr. Malackowski explained that both the Finch and UMN patents provide "equal [value] in contribution" to REBYOTA, and so the "$50 million upfront payment" and the running royalty should apply even if only "one claim from one of the patents" is found to be valid and infringed. *Id.* 506:3–19, 507:4–9. The Federal Circuit has affirmed damages awards in similar circumstances. *Hologic v. Minerva Surgical*, 957 F.3d 1256, 1271 (Fed. Cir. 2020) (upholding "[a] single damages award" where expert explained "that the same royalty rate he used in his damages calculation would apply to either" patent). Ferring's cited cases address factually inapposite circumstances, *e.g.*, separate damages awarded for the asserted patents (*Omega*, 13 F.4th at 1378) or the damages expert admitted he did not apportion (*Mondis Tech. v. LG Elecs.*, 407 F. Supp. 3d 482, 490 (D.N.J. 2019)). Ferring's motion should be denied.

IX. Conclusion

For the foregoing reasons, Ferring's motion for JMOL should be denied.

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